



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

09/831,180

08/03/2001

Chiaki Senoo

50026/027001

1189

21559

7590

04/07/2008

CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

NOTIFICATION DATE

DELIVERY MODE

04/07/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/831,180 | <b>Applicant(s)</b><br>SENOO ET AL. |  |
|                              | <b>Examiner</b><br>SHERIDAN SWOPE    | <b>Art Unit</b><br>1652             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0308</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' Appeal Brief Review request of August 15, 2007 is acknowledged. As per the Notice of Panel Decision from Pre-Appeal Brief Review mailed March 7, 2008, prosecution on this Application is herein reopened.

The current claim set was filed November 27, 2006. Claims 1-14 are pending. Claims 9-14 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Claims 1-8 are hereby reexamined.

#### ***Claim Objections***

Claim 4 is objected to for "fused with other peptide", which should be corrected to fused with another peptide".

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

#### ***Utility***

Rejection of Claims 1-8 under 35 U.S.C. 101/112 because the claimed invention lacks patentable utility, for the reasons explained in the prior actions, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments in their Pre-Appeal Brief Review request of August 15, 2007.

(A) Example 10 of the Utility Guidelines asks whether there was a "well established utility" for the claimed invention: a nucleic acid including a particular sequence homologous to a DNA ligase and answers as follows.

Art Unit: 1652

Based upon applicant's disclosure and the results of the PTO search, there is no reason to doubt the assertion that SEQ ID NO: 2 encodes a DNA ligase. **Further, DNA ligases have a well-established use in the molecular biology art based on this class of protein's ability to ligate DNA.** Consequently the answer to the question is yes...In this case SEQ ID NO: 2 was shown to encode a DNA ligase that the artisan would have recognized as having a specific, substantial and credible utility based on its enzymatic activity. (Applicants' emphasis)

Thus a utility rejection should not have been made.

The present invention is analogous to Example 10. The recited protein belongs to the trypsin-family of proteases, as indicated by the presence of conserved signature motifs including the conserved histidine and serine residues. Prosite indicates if a protein includes both the histidine and serine active site signatures, it is a trypsin family serine protease. Therefore, Tespec PRO-1 is a trypsin-family serine protease.

(B) In most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101 (M.P.E.P. § 2107.02.III.A).

(C) A high degree of sequence homology is not the only way to determine that a protein belongs to a given class. The motifs contained in a protein sequence can be critical to a protein's function, and in some cases provide valuable information for identifying that function. It would be unreasonable for the Office to doubt that the protein of SEQ ID NO: 2 having the serine and histidine active site signatures is a trypsin-family serine protease, irrespective of the degree of sequence homology to any other serine protease.

(D) As per Example 10 of the Utility Guidelines, belonging to a class of proteins is sufficient to provide a specific and substantial utility.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: Applicants' disclosure that the protein of SEQ ID NO: 2 has the trypsin-family conserved histidine and serine residues is not sufficient to convince the skilled

Art Unit: 1652

artisan that, more likely than not, said protein has S1 protease activity. The conserved catalytic residues for trypsin-family protease are histidine, aspartic acid, and serine; histidine and serine alone are not sufficient to catalyze cleavage by a trypsin-family protease as taught by both Rawlings et al, 1994 (Table II) and Perona et al, 1997 (pg 29987, para 3; Fig 1 & 2).

Thus, Applicants' assertion that the protein of SEQ ID NO: 2 has the conserved histidine and serine residues is not sufficient to convince the skilled artisan that, more likely than not, said protein is a trypsin-family protease.

Even if evidence was provided sufficient to convince the skilled artisan that, more likely than not, the protein of SEQ ID NO: 2 is a trypsin-family protease, utility as a trypsin-family protease is not a specific and patentable utility for the following reasons. Example 10 of the Utility Guidelines describes a specification disclosing a novel protein, which has 95% homology to a known DNA ligase. Said specification is not homologous to the instant specification because the protein of SEQ ID NO: 2 does not have high homology to any protein with a demonstrated specific and substantial activity. In addition, the utility for a DNA ligase is specific but utility for a trypsin-family protease is not specific. DNA ligases catalyze a specific and well-characterized enzymatic reaction wherein nucleic acid molecules are covalently linked together. In contrast, as acknowledged by Applicants in their response of January 10, 2007 (Appendix A, pg 1), the trypsin-family of proteases is a large and variable family comprising proteases having a large number of variable cleavage specificities and substrates, having a large number of variable cellular functions, and having the potentiality of being involved in many different diseases. In fact, the trypsin-family has the largest number of proteins with the most diverse activities of any protease family (Rawlings

et al, 1994, Table III). The specification fails to provide evidence, or even assert, that the polypeptide of SEQ ID NO: 2 has the utility of any specific trypsin-like protease or any other specific protease activity.

(B) Reply: It is acknowledged that there is a presumption of utility. This presumption is overturned, however, when the invention fails to have a specific, substantial, and credible utility. In the instant case, the specification fails to even assert a specific utility for the recited protein (see (A) above and prior actions) and provides no evidence for a specific utility. Mere assertion that a protein belongs to a very large and variable class of proteins does not provide a patentable utility.

(C) Reply: It is acknowledged that a high degree of sequence homology is not the only way to determine that a protein belongs to a given class, that motifs contained in a protein sequence can be critical to its function, and that conserved functional motifs provide information on the function of an uncharacterized protein. However, for the reasons explained in (A), above, Applicants' assertion that the protein of SEQ ID NO: 2 has the conserved histidine and serine residues is not sufficient to convince the skilled artisan that, more likely than not, said protein is a trypsin-family protease.

(D) Reply: For the reasons explained in (A) and (B), above, belonging to a large and functionally variable class of proteins is not sufficient to provide a specific and substantial utility.

For these reasons and those explained in the prior action, rejection of Claims 1-8 under 35 U.S.C. 101/112 because the claimed invention lacks patentable utility is maintained.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

Claim 5 is rendered indefinite by recitation of “stringent conditions of 42°C, 2xSSC, 0.1% SDS”. The skilled artisan would know that conditions of 42°C, 2xSSC, 0.1% SDS are not stringent hybridization conditions.

Claim 5 is rendered indefinite by improper antecedent usage. For Claim 5, the phrase “said protein” lacks antecedent basis.

***Allowable Subject Matter***

No claims are allowable.

**Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants’ remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-092834. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652